Safety and cost-efficiëncy of new imaging techniques in addition to cardiac CT-scan in patients with possible coronary artery disease

Gepubliceerd: 26-05-2021 Laatst bijgewerkt: 13-12-2022

We hypothesize that the MACE and mortality rates will be very low, due to mild or absent coronary disease on the CCTA and the short follow-up duration.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20004

Bron
NTR

Verkorte titel
iCORONARY - registry

Aandoening

Coronary artery disease

Ondersteuning

Primaire sponsor: St. Antonius Hospital
Overige ondersteuning: ZonMW doelmatigheidssubsidie

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective of the registry is the event rate of MACE and all-cause mortality in a 12 month follow-up period

Toelichting onderzoek

Achtergrond van het onderzoek

Only small proportion of the 180 000 patients that are referred to a cardiologist each year in the Netherlands with complaints of angina pectoris or shortness of breath suffer from coronary stenosis in such a degree that revascularisation is required. To identify these patients, multiple diagnostic tests are available. Simple non-interventional imaging tests, such as coronary CT-scan, are safe, relatively cheap and can effectively rule-out coronary artery disease. However, when coronary artery disease is present, coronary CT-scan cannot assess the restriction in blood flow caused by the stenosis.

If coronary CT-scan shows no or mild non-flow restricting coronary artery disease, further diagnostic testing is not neccessary. In this registry-part of the iCORONARY trial, these patients are included in a registry in which we will assess outcomes and quality of life at various timepoints until 12 months after undergoing CCTA using questionnaires. Following these patients up ensures we obtain a ‘real-world’ estimate of the ability of CCTA to adequately triage patients with no or low CAD disease burden from patients with intermediate to severe CAD disease burden as practiced in the Netherlands. In other words, it provides us with an estimate of the ability of CCTA to effectively rule out CAD in need of further evaluation.
The primary objective of the registry is the event rate of MACE: all-cause mortality, aborted sudden cardiac death, myocardial infarction and unplanned hospitalization for chest pain leading to urgent revascularization. We hypothesize that the MACE and mortality rates will be very low, due to mild or absent coronary disease on the CCTA and the short follow-up duration.

This study consists of a randomized controlled trial and a patient registry. This is the registration of the patient registry. For the registration of the randomized controlled trial, see registration NL9492

Doel van het onderzoek

We hypothesize that the MACE and mortality rates will be very low, due to mild or absent coronary disease on the CCTA and the short follow-up duration.

Onderzoeksopzet

- Week -2: screening and approaching of possible subjects (after referral for coronary CT-scan)
- Week -1: informing possible subject about study procedure (day of coronary CT-scan)

- Week 0: inclusion, informed consent, first (baseline) questionnaire
- 1 month: second questionnaire
- 3 months: third questionnaire
- 6 months: fourth questionnaire
- 12 months: fifth questionnaire

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- The subject is ≥ 18 years of age
- The subject is willing and able to provide informed consent and adhere to study rules and regulations and follow-up
- The subject has the clinical suspicion of having (recurrent) angina pectoris or an equivalent and suspected coronary artery disease, based on symptoms and signs, history, clinical examination and baseline diagnostic testing (e.g. ECG recording and laboratory tests) as described in the 2019 ESC guideline on chronic coronary syndromes.
- The subject has undergone ≥64 multidetector row coronary CTA as part of usual care deemed by the treating physician, which shows a CAD-RADS score of 0-2

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

- The subject is suffering from unstable angina pectoris.
- The subject is suffering from decompensated congestive cardiac failure.
- The subject is suffering from a known non-ischemic cardiomyopathy.
- The subject has a history of PCI or coronary artery bypass grafting (CABG).
- The subject has had pacemaker or internal defibrillator leads implanted.
- The subject has a prosthetic heart valve.
- There is a severe language barrier.
- The subject participates in any other clinical trial that interferes with the current study.
- Clinical condition prohibiting subsequent interventional therapy as indicated by the results of the imaging procedures.
- The subject is or might be pregnant.
- The subject does not comply or is not able to comply to the imaging guidelines for the performance and acquisition of CCTA by the Society of Cardiac Computed Tomography (SCCT), including:
• The subject is suffering from a cardiac rhythm other than sinus rhythm.
• The subject is morbidly obese (Body Mass Index (BMI) > 40).
• The subject is not able to sustain a breath-hold for 25 seconds.
• The subject is unable to remain in supine position for at least 30 minutes.
• The subject has known allergies to or contra-indications to receiving an iodinated contrast agent. Contraindications to receiving an iodinated contrast agent: Glomerular Filtration Rate (GFR) < 45 ml/min/1,73m2 and if the subject is diabetic or has at least two risk factors for developing contrast induced renal failure a GFR < 60 ml/min/1,73m2.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	14-06-2021

Aantal proefpersonen:	2475
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	26-05-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9495
Ander register	MEC-U : R21.026

Resultaten